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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application Number : 10/656,304  
Applicant(s) : Andrea McPhillips et al.  
Filed : September 5, 2003  
Tech Cntr/AU : 1617  
Examiner : Gina C. Yu  
Entitled : Composition for Inhalation Comprising  
Delta-9-Tetrahydracannabinol in a Semiaqueous Solvent  
  
Attorney Reference : 112689-02972938  
Customer Number : 43569

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97**

Sir:

Pursuant to 37 CFR §1.97 and 1.56, the attention of the U.S. Patent and Trademark Office is hereby directed to the following disclosures made herein, which include:

**REFERENCES AND RELEVANCY**

- ☐ Applicant(s) wish(es) to make of record the documents listed on the attached Form PTO-1449. Copies of the listed documents are attached, where required, as are any readily available full or partial English translations of any non-English language documents.
- ☒ Applicant(s) wish(es) to make of record the documents listed on the attached Form PTO-1449. The references cited herein were cited for consideration in the parent application, and, pursuant to 37 CFR 1.98(d), copies of the cited references can be found in the file of the parent application (*U.S. Serial No. 09/639,289, filed August 15, 2000*).
- ☐ Applicant(s) wish(es) to make of record the documents listed on the attached Form PTO-1449. The references cited herein were cited in the International Search Report issued for the corresponding International application, and copies of the International Search Report and the cited references are attached for the Examiner's consideration.
- ☐ Applicant(s) wish(es) to make of record the documents listed on the attached Form PTO-1449. The references cited herein were cited in a communication from a foreign or international patent office in a counterpart foreign or international application(s), and copies of both the relevant communication and the cited references, where required, are attached for the Examiner's consideration.

### CERTIFICATION

The undersigned certifies that, pursuant to 37 CFR §1.97(e)(1),

- ☐ each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign or international patent office in a counterpart foreign or international application not more than three months prior to the filing of this Statement.

### RELATED CASES

- ☐ Identified in the attached Appendix are related applications directed to related technical subject matter. Copies of the related applications, where required, are attached for the Examiner's consideration. *The identification of the related U.S. patent applications is not to be construed as a waiver of secrecy for those applications, now or upon issuance of the present application as a patent.*

### BASIS FOR CONSIDERATION

This Information Disclosure Statement is filed:

- ☒ within three months of the filing date of the application and/or before the mailing date of a first Official Action on the merits, and no fee is required [37 C.F.R. §1.97(b)].
- ☐ with the appropriate certification, and no fee is required [37 C.F.R. §1.97(e)(1)].
- ☐ after the mailing date of the first Official Action on the merits, but prior to the issuance of a Final Official Action or a Notice of Allowance, and the requisite fee, if necessary, is authorized herein for payment [37 C.F.R. §1.97(c)].
- ☐ after the mailing date of the Final Official Action or Notice of Allowance, but prior to the payment of the issue fee, the requisite certification under 37 CFR §1.97(e)(1) is made herein, and the requisite fee, if necessary, is authorized herein for payment [37 C.F.R. §1.97(d)].
- ☐ with a Request for Continued Examination (RCE), and no fee is required [37 C.F.R. §1.97(b)(4)].

### FEE AUTHORIZATION

- ☒ Authorization is hereby given to charge any deficient fee(s) under 37 CFR §1.16 and §1.17 as necessary to ensure the consideration of this disclosure, or to credit any fee overpayments, to Deposit Account No. 503-121.
- ☐ Authorization is hereby given to charge the requisite fee of \$180 (Fee Code 1806) for submission of this Information Disclosure Statement to Deposit Account No. 503-121.


It is respectfully requested that this information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

The Examiner is further respectfully requested to return of a copy of the enclosed Form PTO-1449 with the Examiner's initials in the left column.

The examination and allowance of this Application is respectfully requested.

Respectfully Submitted,

MAYER BROWN ROWE & MAW LLP

By:   
Christopher M. Beck  
Registration No. 52,603

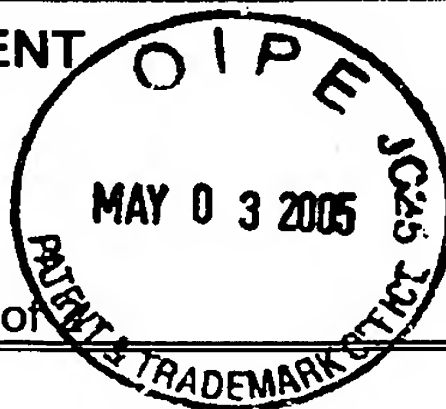
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Date: May 3, 2005

Attachment(s): PTO Form 1449

**INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT**



Attorney Reference: 112689-02972938

Applicant: Andrea McPhillips et al.

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Examiner: Gina C. Yu

Group Art Unit: 1617

**U.S. PATENT DOCUMENTS**

Examiner's Initials*		Document Number	Date MM/YYYY	Name (Family Name of First Inventor)	Class	Sub Class	Filing Date (if appropriate)
	AR	6,294,192	09/2001	Patel et al.			
	BR	4,635,651	01/1987	Jacobs.			
	CR	4,933,363	06/1990	EISohly.			
	DR	5,258,336	11/1993	LaMastro et al.			
	ER	5,447,729	09/1995	Belenduik et al.			
	FR	5,492,688	02/1996	Byron et al.			
	GR	5,502,076	03/1996	Dixit et al.			
	HR	5,508,023	04/1996	Byron et al.			
	IR	5,508,037	04/1996	EISohly.			
	JR	5,540,934	07/1996	Touitou			
	KR	5,635,530	06/1997	Mechoulam et al.			
	LR	5,716,638	02/1998	Touitou			
	MR	5,736,124	04/1998	Akehurst et al.			
	NR	5,804,592	09/1998	Volicer.			
	OR	5,847,128	12/1998	Martin et al.			

**FOREIGN PATENT DOCUMENTS**

		Document Number	Date MM/YYYY	Country			Translation Readily Available		English Abstract	
							Enclosed	No	Enclosed	No
	PR	WO 98/29096	07/1998	WO						
	QR	WO 99/32107	07/1999	WO						
	RR	WO 00/24362	05/2000	WO						
	SR	WO 00/27359	05/2000	WO						
	TR	WO 01/13886	03/2001	WO						

**OTHER (Including in this order Author, Title, Periodical Name, Date, Pertinent Pages, etc.)**

	UR	Allison's Apothecary. Our Amber Glass Bottles. 1999.*
	VR	Williams, et al., "Bronchodilator Effect of Delta-Tetrahydrocannabinol Administered By Aerosol to Asthmatic Patients," Thorax, vol. 31 (No. 6), p. 720-723, (1976).
	WR	Lichtman, et al., "Pharmacological Evaluation of Aerosolized Cannabinoids in Mice," European Journal of Pharmacology, vol. 399 (No. 2-3), p. 141-149, (2000).
	XR	Ault, "Techniques and Experiments for Organic Chemistry," Waveland Press, Inc. (Prospect Heights, Illinois), p. 44-50, 183-194, (1987).
	YR	Dedhiya, et al., "Current Concepts for Delivery of D-9 THC: Prospects For Cannabinoid Drug Development," (1998).
	ZR	Vachon, et al., "Airways Response to Aerosolized Delta-9-Tetrahydrocannabinol: Preliminary Report," The Therapeutic Potential of Marijuana, Plenum Medical Book Company (New York and London), p. 111-121, (1976).
	AAR	Fratello, "NIH Study Helps the Case For Medical Marijuana," The Sacramento Bee, (Sep. 5, 1997).
	BBR	Lewis, "Just Say `Research`," The Scientist, vol. 12 (No. 3), p. 1&6, (Feb. 2, 1998).
	CCR	"Aerosol Delivery: Stability Data" (Feb. 18, 1998).

Examiner

Date Considered:

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



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Group Art Unit: 1617

**U.S. PATENT DOCUMENTS**

Examiner's Initials*		Document Number	Date MM/YYYY	Name (Family Name of First Inventor)	Class	Sub Class	Filing Date (if appropriate)
	AR	5,874,443	02/1999	Kiely et al.			
	BR	5,916,540	06/1999	Akehurst et al.			
	CR	5,922,306	07/1999	Akehurst et al.			
	DR	5,939,429	08/1999	Kunos et al.			
	ER	6,162,829	12/2000	Burstein			
	FR						
	GR						
	HR						
	IR						
	JR						
	KR						
	LR						
	MR						
	NR						

**FOREIGN PATENT DOCUMENTS**

		Document Number	Date MM/YYYY	Country			Available		Abstract	
							Enclosed	No	Enclosed	No
	OR									
	PR									
	QR									

**OTHER (Including in this order Author, Title, Periodical Name, Date, Pertinent Pages, etc.)**

	RR	Little, "Studies of Stability and Purification of Delta 9-Tetrahydrocannabinol," (Nov. 1970).
	SR	Garrett, et al., "Physicochemical Properties, Solubility, and protein Binding of Delta 9-Tetrahydrocannabinol," Journal of Pharmaceutical Sciences, p. 1056-1064, (1974).
	TR	Ohlsson, et al., "Plasma Delta-9-Tetrahydrocannabinol Concentrations and Clinical Effects After Oral and Intravenous Administration and Smoking," Clinical Pharmacology and Therapeutics, vol. 28 (No. 3), p. 409-416, (Sep. 1980).
	UR	Perez-Reyes, et al., "Pharmacology of Orally Administered Delta-9-Tetrahydrocannabinol," Clinical Pharmacology and Therapeutics, vol. 14 (No. 1), p. 48-55, (1973).
	VR	Tashkin, et al., "Bronchial Effects of Aerosolized Delta-9-Tetrahydrocannabinol in Healthy and Asthmatic Subjects," American Review of Respiratory Disease, p. 57-65, (1977).
	WR	Vachon, L. et al, Airways Response to Aerosolized Delta-9-Tetrahydro-Cannabinol: Preliminary Report, The Therapeutic Potential of Marijuana, 1976, Chapter 8, 111-121, Plenum Medical Book Company, New York, US.
	XR	Williams, S.J. et al, Bronchodilator effect of delta-tetrahydrocannabinol administered by aerosol to asthmatic patients, Thorax, 1976, 720-723, vol. 31, No. 6.
	YR	Lichtman, A. et al, Pharmacological Evaluation of Aerosolized Cannabinoids in Mice, European Journal of Pharmacology, 2000, 141-149, vol. 399, No. 2-3.

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